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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/364,847 07/30/99 PEOPLES

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EXAMINER

STEADMAN, D

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

05/01/01

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/364,847

Applicant(s)

PEOPLES ET AL.

Examiner

David J. Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04/06/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Status of the Application

Claims 1-6 are pending.

The amendment of claims 1 and 2 in Paper No. 11, filed 04/10/01 is acknowledged.

Applicants' arguments filed on 04/10/01, Paper No. 11, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

It is noted that Applicants have acknowledged the Examiner's request for additional copies of references cited in form PTO-1449 and will submit additional copies of references filed with the Information Disclosure Statement as requested by the Examiner. These references will be fully considered upon receipt.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulow et al. (Trends Biotech 9:226-231, 1991) in view of Peoples et al. (J Biol Chem 262:97-102, 1987) and Peoples et al. (Mol Microbiol 3:349-357, 1989). Claims 1-3 are drawn to a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme with a linker between zero and 50 amino acids. Claim

6 is drawn to expression of a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme in a bacteria.

The rejection was fully explained in the previous Office action.

Applicants argue that Bulow et al. teach only general advantages of a fusion enzyme and do not specifically teach the advantages of a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme. Applicants further argue that the advantages of a fusion protein as taught by Bulow et al. are not sufficient to provide the necessary motivation to fuse enzymes for the manipulation of biosynthetic pathways of PHA production. This is not found persuasive because Peoples et al. (1989) clearly teach that the product of the β -ketothiolase reaction is subsequently metabolized by acetoacetyl coenzyme A reductase (p 349, Introduction) and, based on the general advantages of using a fusion enzyme as taught by Bulow et al., in particular proximity effects whereby an intermediate product can be transferred efficiently to the desired second enzyme, instead of a competing enzyme (page 226), it would have been obvious to one of ordinary skill in the art for a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme.

2. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bulow et al. in view of Peoples et al. (1987) and Peoples et al. (1989) as applied to claims 1-3 and 6 above and further in view of Argos (J Mol Biol 211:943-958, 1990). Claim 4 is drawn to a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme with a glycine-serine linker.

The rejection was fully explained in the previous Office action.

Applicants argue that Argos teaches a fusion polypeptide linker using glycine, serine, and threonine, and therefore, Argos does not disclose a linker of only glycine and serine residues. This is not found persuasive because, although Argos does not specifically teach a linker

composed of only serine and glycine residues, Argos specifically teaches “pentapeptides with only Gly, Ser, and Thr would make the best general linkers as these residues occur most often” and “are strongly preferred by natural linkers” (p 947, left column) and that “[Gly, Ser, and Thr] are all relatively small with glycine providing flexibility and serine and threonine being polar to interact with solvent”. Argos does not teach that a peptide linker without threonine is deleterious or disadvantageous and one of ordinary skill in the art would have recognized that serine and threonine each provide the same advantage to the linker (i.e., solvent interaction) such that either or both could be used for this purpose and, therefore, a peptide linker could at least consist of Gly for flexibility and Ser for solvent interaction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme with a linker consisting of glycine-serine residues.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bulow et al. in view of Peoples et al. (1987) and Peoples et al. (1989) as applied to claims 1-3 and 6 above and further in view of Somerville et al. (US Patent 5,610,041, 1997). Claim 5 is drawn to expression of a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme in a plant.

The rejection was fully explained in the previous Office action.

Applicants argue that the motivation of Somerville et al. to produce PHA/PHB in genetically engineered plants, namely reduced cost of production, is not a motivation which would lead one of ordinary skill in the art to a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme expressed in a plant. This is not found persuasive because, while the teachings of Somerville et al. taken alone would not provide motivation for a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme expressed in a plant, as stated in the previous Office action, the


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teachings of Somerville et al. combined with the teachings of Bulow et al. would provide sufficient motivation for one of ordinary skill in the art to produce PHA/PHB in plants expressing a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme. One of ordinary skill would have recognized that a plant expressing a β -ketothiolase-acetoacetyl CoA reductase fusion enzyme would exhibit increased PHA/PHB synthesis due to the favorable kinetics and proximity effects as taught by Bulow et al.

4. No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The examiner can normally be reached Monday-Friday from 8:00 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Art Unit is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman


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